

Message Text

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DRAFTED BY: DHEW/ASH/PHS/OIH:LAVOGEL

APPROVED BY: SCI:GYOUNTS

NBS:DR ROBERT SCHAFFER (SUBS)

DHEW/NIH:RMELVILLE

DHEW/OS:ROEGEBERG (SUBS)

EPA:THARRIS (SUBS)

EUR/RPM:DTELLEEN

EUR/CE:LHEICHLER

OES/SCI/BMP:MSBEAUBIEN

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SUBJ: OFFSET AGREEMENT - HEALTH PROJECTS

SUMMARY/ 1. IN VIEW LACK DIFINITIVE HEALTH PROPOSALS FROM FRG FOR OFFSET FUNDING, DESPITE THEIR INDICATED INTEREST IN COOPERATION THIS AREA, DHEW HAS PROPOSED THAT EMBASSY PRESENT FOR FRG'S CONSIDERATION A PROPOSAL DIRECTED TOWARD ASSESSING THE IMPACT OF A STANDARD REFERENCE METHOD ON INTERNATIONAL CLINICAL LABORATORY PRACTICE. THIS PROPOSAL IS ENDORSED BY SCI AND EUR BECAUSE OF ITS POTENTIAL BENEFIT WITH RESPECT TO NATO ACTIVITIES AND POTENTIAL FOR THIRD COUNTRY INVOLVEMENT, WHILE PROVIDING VALUABLE INFORMATION THAT COULD LEAD TO UNIVERSAL ADVANCES IN ACCURACY OF CLINICAL LABORATORY TESTING. END SUMMARY.

2. THE U.S. DEPARTMENT OF HEALTH, EDUCATION AND WELFARE HAS UNCLASSIFIED

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RECOMMENDED THAT A PROPOSED PROJECT TO ASSESS THE IMPACT OF

A STANDARD REFERENCE METHOD ON INTERNATIONAL CLINICAL LABORATORY PRACTICE BE PRESENTED TO THE FRG FOR CONSIDERATION FOR OFFSET FUNDING. THE PROJECT IS AN OUTGROWTH OF THE NATO/CCMS ADVANCED HEALTH CARE PILOT STUDY, AUTOMATION OF CLINICAL LABORATORIES PROJECT. THE FRG HAS BEEN A LEADING PARTICIPANT IN THIS PROJECT ALONG WITH THE U.S., U.K., ITALY, PORTUGAL, BELGIUM, DENMARK, CANADA, AND FRANCE. ONE OF THE RECOMMENDATIONS FROM THIS PROJECT IS THAT A PILOT STUDY BE INITIATED TO ASSESS THE IMPACT OF A STANDARD REFERENCE METHOD ON INTERNATIONAL CLINICAL LABORATORY PRACTICE. THE AREA CHOSEN FOR THIS PILOT STUDY IS IRON (FE) IN BIOLOGICAL MATERIALS.

3. IT IS CONTEMPLATED THAT THE STUDY WOULD BE CONDUCTED ALONG TWO LINES. FIRST, THE PROBLEM OF ACCURATELY MEASURING IRON AND RELATING THIS TO A TRUE VALUE (BASE-LINE METHOD) BY ISOTOPE DILUTION-MASS SPECTROMETRY WOULD BE SOLVED. SECONDLY, THE APPLICATION OF THE BASE-LINE METHOD OF ANALYSIS TO A CANDIDATE METHOD FOR BIOLOGICAL MATERIALS SUCH AS SERUM AND RED BLOOD CELLS (HEMOGLOBIN) WILL BE ATTACKED. SINCE IRON EXISTS IN BIOLOGICAL MATERIALS IN DIFFERENT FORMS SUCH AS INORGANIC (FE PLUS PLUS AND FE PLUS PLUS PLUS) PROTEIN BOUND (TRANSFERRIN) AND COMPLEXED TO PHOSPHATES AND PORPHYRINS, IT IS PROPOSED THAT THE MEASUREMENT OF IRON IN ITS VARIOUS BIOLOGICAL FORMS BE INCLUDED IN THE STUDY, AFTER THE BASIC IRON ANALYSIS METHOD HAS BEEN DEVELOPED.

4. THREE MAJOR COMPONENTS ARE REQUIRED FOR THE ORGANIZATION OF THE PROPOSED STUDY: (A) AN EXPERTS GROUP OF FOUR TO EIGHT SCIENTISTS, LEADERS IN THE PARTICULAR METHODOLOGY UNDER STUDY, TO DEFINE THE PROBLEM, SET THE ACCURACY GOAL FOR THE REFERENCE METHOD, RECOMMEND AND HELP RECRUIT THE COOPERATING LABORATORIES, AND CHOOSE THE CANDIDATE METHOD. THE EXISTING CCMS WORKING GROUP COULD SERVE AS THIS GROUP. (B) A COORDINATING LABORATORY TO COORDINATE THE ONGOING WORK-SET SCHEDULES, OBTAIN AND DISTRIBUTE SAMPLES, PROTOCOL, DATA SHEETS, ETC., HELP DEVELOP PROTOCOL, GATHER AND ANALYSE DATA, AS WELL AS DEVELOP AND PROVE A BASE-LINE METHOD. THE U.S. NATIONAL BUREAU OF STANDARDS HAS THE NECESSARY EXPERTISE AND IS WILLING TO DO THIS. (C) EIGHT TO TWELVE COOPERATING LABORATORIES (ONE FROM UNCLASSIFIED

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EACH OF THE COUNTRIES PARTICIPATING IN THE CCMS PROJECT) TO PERFORM THE ACTUAL LABORATORY TESTS ON THE SUPPLIED SAMPLE USING THE DEVELOPED PROTOCOL. THE INDIVIDUAL PARTICIPATING LABORATORIES WOULD THEN BE IN A POSITION TO COORDINATE THE IMPROVEMENTS IN THIS METHODOLOGY THROUGHOUT THEIR RESPECTIVE COUNTRIES.

5. BASED ON PREVIOUS SIMILAR WORK PERFORMED BY THE NBS ON

ANOTHER REFERENCE METHOD THE PROJECT WOULD MOST LIKELY REQUIRE TWO YEARS. THE TOTAL COST IN THE U.S. WOULD BE ABOUT DOLS 300,000. THIS MONEY WOULD COVER THE COSTS INVOLVED IN DEVELOPMENT AND ISSUING THE STANDARD REFERENCE MATERIAL FOR IRON AND FOR THE COORDINATION OF ACTIVITIES BOTH AT THE NATIONAL AND INTERNATIONAL LEVEL.

6. THIS PROJECT WOULD HAVE IMPORTANT IMPLICATIONS FOR UNIVERSAL ACCURACY IN CLINICAL LABORATORY PRACTICE, WITH OBVIOUS PRACTICAL BENEFITS FOR THE U.S., FRG AND OTHER COUNTRIES.

7. THE FRG TECHNICAL EXPERT FOR THIS PROJECT, DR. AXEL DELBRUCK, CAN PROVIDE ADDITIONAL TECHNICAL INFORMATION SINCE HE PARTICIPATED IN THE MEETINGS WHERE THIS PROJECT WAS DISCUSSED.

8. REQUEST EMBASSY PRESENT THIS PROPOSAL TO FRG AT APPROPRIATE TIME AND AS ANOTHER EXAMPLE OF THE TYPE PROJECT WE HAD IN MIND WHEN CIVILIAN R&D CONCEPT WAS INCLUDED IN OFFSET AGREEMENT. KISSINGER

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